

Appendix C. Multi Active Ingredient Analysis

PRODUCT FORMULATIONS CONTAINING MULTIPLE ACTIVE INGREDIENTS

The Agency does not routinely include, in its risk assessments, an evaluation of mixtures of active ingredients, either those mixtures of multiple active ingredients in product formulations or those in the applicator's tank. In the case of the product formulations of active ingredients (that is, a registered product containing more than one active ingredient), each active ingredient is subject to an individual risk assessment for regulatory decision regarding the active ingredient on a particular use site. If effects data are available for a formulated product containing more than one active ingredient, they may be used qualitatively or quantitatively^{1 2}.

There are no definitive product LD50 values, with associated 95% Confidence Intervals (CIs) available for captan. A limit dose test was done for several captan formulations (Table C.1).

As discussed in USEPA (2000) a quantitative component-based evaluation of mixture toxicity requires data of appropriate quality for each component of a mixture. In this mixture evaluation an LD50 with associated 95% CI is needed for the formulated product. The same quality of data is also required for each component of the mixture. Given that the formulated products for captan do not have LD50 data available it is not possible to undertake a quantitative or qualitative analysis for potential interactive effects. However, because the active ingredients are not expected to have similar mechanisms of action, metabolites, or toxicokinetic behavior, it is reasonable to conclude that an assumption of dose-addition would be inappropriate. Consequently, an assessment based on the toxicity of captan is the only reasonable approach that employs the available data to address the potential acute risks of the formulated products.

¹ Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, Environmental Protection Agency (January 2004) (Overview Document).

² Memorandum to Office of Prevention, Pesticides and Toxic Substance, US EPA conveying an evaluation by the U.S. Fish and Wildlife Service and National Marine Fisheries Service of an approach to assessing the ecological risks of pesticide products (January 2004).

Table C.1. Pesticide Products Formulated with Captan and Other Pesticide Active Ingredients

CAPTAN PRODUCTS ^{i ii}

PRODUCT/TRADE NAME	EPA Reg.No.	% Captan	PRODUCT		ADJUSTED FOR ACTIVE INGREDIENT	
			LD ₅₀ (mg/kg)	CI (mg/kg)	A.I Adjusted CI (mg/kg)	A.I Adjusted LD50 (mg/kg)
Bonide Fruit Tree Spray	4-59	5.87	>5000	NA Limit Dose	NA Limit Dose	NA Limit Dose
Bonide A Complete Fruit Tree Spray	4-122	11.76	No Data	No Data	No Data	No Data
Bonide Home Orchard Spray	4-355	6.03	No Data	No Data	No Data	No Data
Gustafson Vitavax PC Peanut Seed Treatment Fungicide	264-949	45	>5050	NA Limit Dose	NA Limit Dose	NA Limit Dose
Four Way Peanut Seed Treatment Fungicide	264-998	49	>5000	NA Limit Dose	NA Limit Dose	NA Limit Dose
Three Way Peanut Seed Treatment Fungicide	264-999	49	>5000	NA Limit Dose	NA Limit Dose	NA Limit Dose
Gustafson Rival Flowable Systemic Fungicide	400-528	19.8	>5050	NA Limit Dose	NA Limit Dose	NA Limit Dose
Rival Pak	400-531	19.8	No Data	No Data	No Data	No Data
Sorghum Guard	400-532	32.75	CANCELLED 07/16/07			
Gustafson Captan Lindane 12.5-25	400-539	12.23	CANCELLED 07/16/07			
Gustafson Vitavax Captan 20-20 Seed Protectant	400-554	19.55	>5000	NA Limit Dose	NA Limit Dose	NA Limit Dose
Gustafson Vitavax Captan 12.5-25 Seed Protectant	400-555	24.4	>5000	NA Limit Dose	NA Limit Dose	NA Limit Dose

			PRODUCT		ADJUSTED FOR ACTIVE INGREDIENT	
PRODUCT/TRADE NAME	EPA Reg.No.	% Captan	LD ₅₀ (mg/kg)	CI (mg/kg)	A.I Adjusted CI (mg/kg)	A.I Adjusted LD50 (mg/kg)
Bean Guard/Allegiance	400-561	25	5519	No Data	1380	No Data
FERTI.LOME Liquid Fruit Tree Spray	7401-438	9.78	No Data	No Data	No Data	No Data
CaptEvate 68 WDG Fungicide	66330-48	53.6	>2000	No Data	No Data	No Data

ⁱ From registrant submitted data to support registration. Compiled by Office of Pesticide Programs Health Effects Division.

ⁱⁱ Captan LD50= 9000 mg/kg; CI= N/A